Drug Symposium Workshop

- Disciplinary Focused Workshops
- Case Study Review of Chronic Pain Patients
- October 16, 2014
  - Brian McCrate, Pharm.D., BCPS, Clinical Pharmacist of Internal Medicine, University Department of Pharmacy, IU Health
  - Paula A. Bowers, B.S.Pharm., J.D. Wal-Mart Pharmacy, Noblesville, IN

Prescription Drug Abuse Symposium 2014

- Discussion of Scenario One
  - New Physician
    - Communication
      - INSPECT
      - HIPAA Issues
      - Discontinue
        - Legal Aspects

Section 1:
Clinical Considerations

- Pain Management Prescribing Emergency Rule
  - Patient Qualifications
  - Prescriber Expectations
  - Pain Contracts

- INSPECT Utilization
  - Determining suspicious behavior
  - Limitations
  - Useful Functions

- Opioid Emergency Supply - Alternative Medications

- Potential Pitfalls of Rejected Patients
  - Overuse of OTC Products
  - Potential Prescribing Shifts
  - Financial considerations

Prescription Drug Abuse Symposium2014

- Discussion
- Scenario Two
- Addiction
- Abuse
- Maintenance and Detoxification
- Changes in Rules

Section 2:
Clinical Considerations

- Opioid Alternatives
  - Neuropathic Pain
  - Adjuvant Medications
  - Nuerolytic Block & Implantable Devices
- Opioid Conversion - Limitations and Considerations
- Downward Titration of Opioids
- Potential Dangers of Polypharmacy

C-II (Schedule II)
vs. C-III (Schedule III)

C-II : A drug or other substance with HIGH abuse potential that has an accepted medical use in the U.S. (with severe restrictions) and the abuse of which may lead to SEVERE psychological or physical dependency.

C-III : A drug or other substance with potential for abuse less than C-I and II that has an a currently accepted medical use in the U.S. and the abuse of which may lead to *moderate or low* physical dependence or HIGH psychological dependency.

Changes to Schedules of Medications

- Hydrocodone
  - C-III to C-II
- Tramadol
  - Non-Controlled to C-IV
- Other prescription medications of concern

Reclassification of drugs

- IC 35-48-2-14 The Indiana Board of Pharmacy has authority to reclassify drugs by rule. The classification of a drug has to be in conformance with a similar move at the federal level.

- Drugs may be reclassified from a more restrictive to a less restrictive schedule or designated a controlled substance when they were previously not controlled.

Who may prescribe a CS in Indiana?

- The term “practitioner” is not defined in federal law and that is left to the states. In Indiana, only seven licensed persons are authorized to prescribe at all, and only six of those persons are authorized to register with the DEA to prescribe controlled substances
  - Physicians
  - Dentists
  - Veterinarians
  - Podiatrists
  - Advanced Practice Nurses (APNs) *** (IN only)
  - Physician Assistants. *** (restrictions)
    - The practitioner NOT permitted to prescribe CS is the Optometrist

C-II Errors on the Rx

- Altering a C-II Rx if something is wrong or missing
  - Pursuant to clarifying a mistake on the prescription withe the authorizing practitioner, items can be changed—-documentation needs to be done.
  - 3 Untouchable Items
    - 1) Patient Name
    - 2) Drug Name
    - 3) Signature of the prescribing practitioner
- If any of the above three are wrong, the Rx should not be filled and patient needs to obtain a new prescription from the authorizing practitioner.
- DEA letter of guidance, October 15, 2008

Legitimate Medical Purpose

- 21 CFR 1306.04 and 856 IAC 2-6-3
  - A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.
    - Scope of Practice
    - Physician-Patient Relationship

Corresponding Liability

- 856 IAC 2-6-3 Purpose of prescription; prohibitions

- (a) A prescription for a controlled substance to be effective ***must*** be issued for a ***legitimate medical purpose*** in a ***reasonable quantity*** by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing ***and*** dispensing of controlled substances is upon the prescribing practitioner but a corresponding responsibility rests with the pharmacist who fills the prescription. (emphasis added)

Requirements for CS Rxs

- 21 CFR 1306.21, 856 IAC 2-6-1.5
  - All prescriptions ***must be signed by the practitioner*** if received in written form or electronically signed in accordance with applicable federal regulations
- 856 IAC 2-6-3
  - Legitimate medical purpose (corresponding liability)
- IF in written form and from IN must be on Security Feature Prescription Blank (856 IAC 1-34-1)
  - Exemptions include telephone Rx, Fax Rx, transfer Rx and out of state Rx.

Emergency Prescribing for C-II Drugs

- 21 U.S.C 290.10
  - What is an Emergency?
    1) Immediate administration of a controlled substance is necessary for the proper treatment of the intended ultimate user; AND 2) No appropriate alternative treatment is available, including the administration of a non C-II drug; AND 3) it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the drug, prior to the dispensing.

  - IF it has been established that an emergency script for a C-II medication is necessary, then what?

Rules for Dispensing an Emergency C-II Medication

- 1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the *emergency period*

- 2) The prescription is immediately reduced to writing by a pharmacist and contains all the required information.

- 3) If the prescriber is not known to the pharmacist, a reasonable effort must be made to verify the authenticity of the Rx

- 4) Within 7 days after the emergency authorization, the practitioner causes a written, signed prescription, dated with the emergency date, to be delivered to the pharmacist (a “covering” Rx) with “Authorization for Emergency Dispensing” noted on the face of the Rx.

- If NOT received, the pharmacist is *required* to notify the nearest DEA office. The covering Rx has to be the same as the emergency phone-in.

Duty to Honor Filling Prescriptions

- IC 25-26-13-16(a)
- A pharmacist shall exercise the pharmacist's professional judgment in the best interest of the patient's health when engaging in the practice of pharmacy.
- IC 25-26-13-16(b)
  - A pharmacist has a duty to honor all prescriptions from a practitioner or from a physician, podiatrist, dentist, or veterinarian licensed under the laws of another state. Before honoring a prescription, the pharmacist *shall take reasonable steps* to determine whether the prescription has been issued in compliance with the laws of the state where it originated. The pharmacist is immune from criminal prosecution or civil liability if the pharmacist, in good faith, refuses to honor a prescription because, in the pharmacist's professional judgment, the honoring of the prescription would:
    - (1) be contrary to the law;
    - (2) be against the best interest of the patient;
    - (3) aid or abet an addiction or habit;
    - (4) be contrary to the health and safety of the patient…….
- If the pharmacist refuses to honor a prescription under (2) or (4), the pharmacist shall notify the physician who issued the prescription not more than 24 hours after prescription is presented to the pharmacy.

INSPECT

- Implementation
- Procedure
- Questions
- Who is authorized to use
- HIPAA concerns

Section 1:
Clinical Considerations

Pain Management Emergency Rule

- Patients who are prescribed for more than three consecutive months:
  - >60 opioid-containing pill per month or
  - A morphine equivalent dose >15mg/day
    - Transderman Fentanyl, hydrocodone extended release, and tramadol (>60mg of morphine equivalent)

- Exclusion
  - Terminal medical condition, residents of licensed health facility, patients enrolled in a licensed hospice program, patient in in/oupatient palliative care program

Daily Opioid Max

Medication	mg/day	mg/day
Morphine	**15**	**60**
Codeine	100	400
Tramadol	-	240
Hydrocodone	15	60
Oxycodone	10	40
Oxymorphone	5	20
Hydromorphone	4	15
Methadone	4	15
Fentanyl Patch	Any Strength	25mcg/hr

Pain Management Emergency Rule

- Core Elements
  - Patient Assessments
  - Treatment Plan
  - Informed Consent
  - Periodic In-Person Visits
  - Compliance
    - INSPECT
    - Drug Tests
    - Contract
  - High Dose Warning (>60mg morphine equivalents)

Pain Management Emergency Rule

- Treatment Agreements
  - Must be signed by practioner and patient
  - Include
    - Goals of treatment
    - Patient's consent to drug monitoring in "circumstances where the physician determines the drug monitoring testing is medically necessary
  - Prescribing policies
  - Requirement that practioner is notified of any other opioid prescriptions
  - Reason for change in therapy or discontinuation
  - Grant physician permission to conduct random pill counts

INSPECT

- **What determines suspicious behavior?**
- **Limitations**
  - Reporting Entities
  - Incorrect Patient Identifiers
  - Retrospective Data
  - System Hiccups
- **Useful Functions**
  - Unsolicitated Requests

Opioid Emergency Supply - Alternative Medications

- Verbal Order for CII
- Tramadol
- Codiene
- NSAIDs
- Acetaminophen
- Lidocaine Patch
- Capsaicin Cream
- Medications for Neuropathic Pain

Potential Pitfalls of Rejected Patients

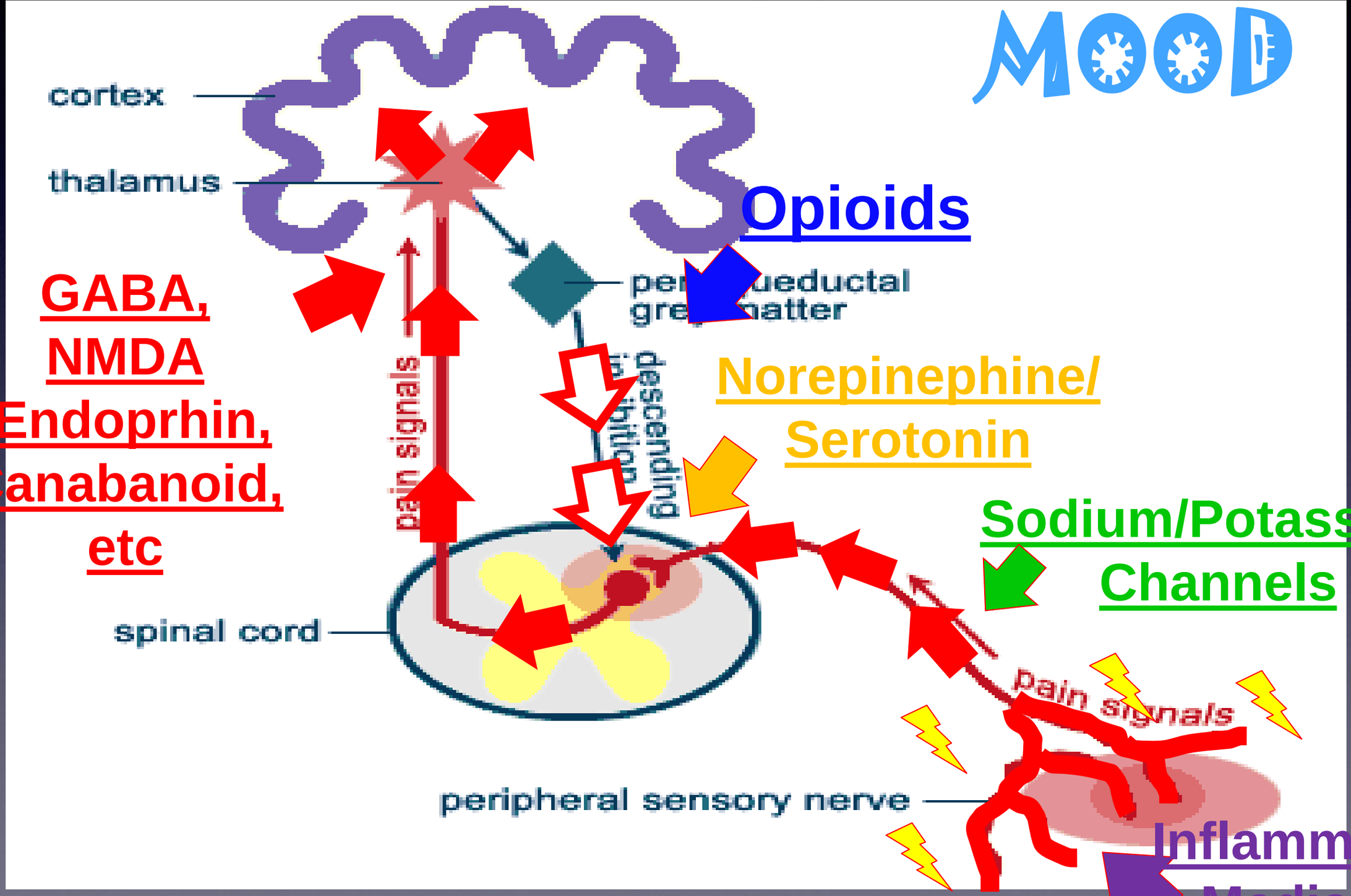
- Overuse of OTC Products
- Potential Prescribing Shifts
- Financial Limitations
- Other Considerations

Section 2:
Clinical Considerations

Pharmacologic Interventions

- Non-opioids
  - Acetaminophen
  - NSAIDs
- Opioids
  - codeine
  - morphine
  - hydrocodone,
  - oxycodone,
  - hydromorphone
  - methadone, fentanyl
  - tramadol, tapentadol
  - buprenophrine
- Co-analgesics
  - Tricylic antidepressants
  - Gabanoids
  - Selective norepinephrine reuptake inhibitors
  - Anticonvulsants
  - Alpha Agonist
  - Ketamine
  - Capsaicin
  - Muscle relaxants
  - Antispasmatics

Mechanism of Action



http://brainchemist.wordpress.com/2010/11/28/pain-sites-of-origin-pathways-and-neurotransmitters/

Consideration for Adjuvant Medications

- Correct identification of pain
- Optimization of therapeutic and non-therapeutic profiles
- Avoidance of poly-pharmacy & side effects
- Sufficient trial on medication
- Patient education
- Cost

Invasive Procedures

- Regional analgesia
- Neurolytic blockade
- Neuroablative surgery
- Implantable devices

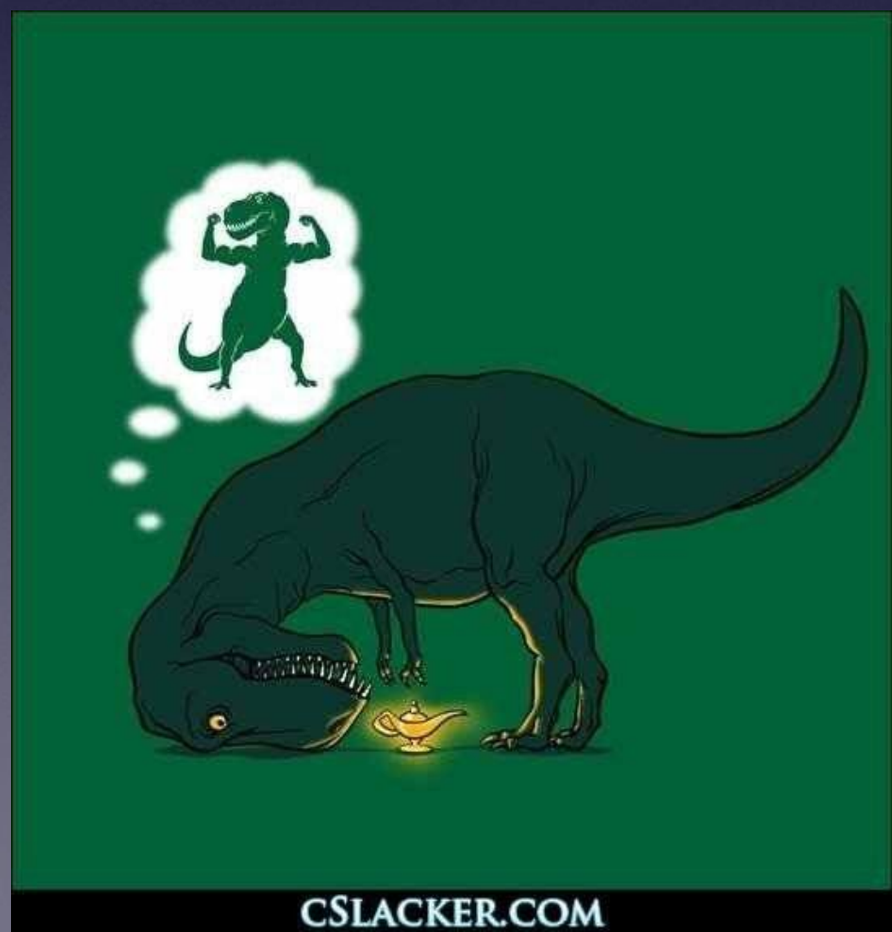
Equianalgesic

Medication	Oral (mg)	IV (mg)
Morphine	30	10
Tramadol	120	-
Codeine	200	-
Hydrocodone	30	-
Oxycodone	20	-
Oxymorphone	10	1
Hydromorphone	7.5	1.5
Fentanyl	-	0.1

McPherson, ML. Demystifying Opioid Conversion Calculations: A Guide for Effective Dosing. Amer Soc of Health-Systems Pharm, Bethesda, MD 2010.

Limitations

- Chart is based on multiple studies with small patient populations and single dose studies
- Some data based on chronic use
- Patient variability
  - Absorption
  - Metabolism & Excretion
  - Age
  - Acuity of illness
  - Incomplete cross tolerance



Discontinuing Opioids

- Slow Titration
  - Lack of benefit in sx or function, opioid induced hyper-analgesia, excessive dose
  - Taper
    - By 10% of total dose q1-2weeks, then once at 20% of dose titrate down by 5% of dose to goal

- **Rapid Titration**
  - Violation of contract, non-compliance with treatment plan, workplace hazard
  - Taper
    - By 20-25% every 3 to 5 days
    - Monitor for withdrawal. May require clonidine, promethazine/ondansetron, and non-opioid sleep aid for symptom management

Discontinuing Opioids

- <u>Immediate Discontinuation</u>
  - Medication diversion, prescription forgery, threats made by patient – Contact law enforcement if needed
  - Suicidal ideation – Immediate referral and re-assessment (Indiana Suicide Hotline 877-968-8454)
  - Rescreen patients periodically for substance use/abuse and co-morbid psychiatric illness